DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
HFI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

September 23, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ronald S. Corbett, President
Boardwalk Inc.
1001 Baytree Road
Valdosta, Georgia 31602

WARNING LETTER

Dear Mr. Corbett:

On May 1 & 4, 1998, Investigator B. Douglas Brogden conducted a Field Test of the Sunlamp Products in use in the tanning booth, [redacted]; at Boardwalk Incorporated located at 1001 Baytree Road, Valdosta, Georgia 31602. This field test revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The following instance of non-compliance with the Federal Performance Standard for Sunlamp Products (21 CFR 1040.20) were noted:

The sunlamp product was found to be in violation of Section 502(j) of the Act, in that this medical device (tanning booth) presents a danger to health when used in the manner, frequency, or duration of its suggested or intended use. You could provide no assurance that the ultraviolet lamps in use were appropriate for use in sunlamp products for the purpose of inducing skin tanning. The ultraviolet lamps in the booth were labeled in red color. In fact, in this instance this red labeling is intended as a warning to denote that the bulbs are intended for medical and/or industrial use and not for skin tanning purposes.

The replacement ultraviolet lamps that were in use in the tanning booth at the time of the inspection, [redacted]watt single pin base, are equivalent to the bulb, [redacted]watt single pin base bulb, which is the manufacturer's, [redacted] recommended bulb for this model tanning booth.

However, at this time this type of ultraviolet lamp can no longer be used to induce skin tanning. This type ultraviolet lamp now has only medical and/or industrial applications, and

the use in a sunlamp product could possibly cause harm to the user of the tanning booth in which these bulbs were in use.

You agreed during the inspection to take the tanning booth out of operation until you were advised by FDA of the safety of the bulbs for use in the tanning booth. This is to advise you that the tanning booth can not be used with the [redacted] or its successor, [redacted] bulbs numbered [redacted] watt single pin base, or any other ultraviolet lamp labeled for medical, industrial or germicidal use. Again, the use of this type ultraviolet lamp in the tanning booth could possibly cause harm to the user.

The sunlamp product, which is an older model tanning booth, should be evaluated for its fitness for use in 1998, considering that the manufacturers originally recommended ultraviolet lamp can no longer be purchased for use in the tanning booth.

Due to the potential health hazard involved with the use of the booth, it is suggested that this booth not be used until appropriate corrections have been made. Failure to take prompt corrective action may result in regulatory action without further notice. These actions include seizure, injunction, and/or civil penalties.

You should notify this office in writing, within fifteen (15)working days of this letter, of all the steps you have taken or intend to take to correct the above violations. You should immediately discontinue use of this booth until it is in compliance with the law. Your response should be addressed to John J. McCall, Compliance Officer, at the address listed in the letterhead.

Sincerely Yours,

Ballard H. Graham
Director, Atlanta District